JUN 2 1 2012

510(k) Summary

Life Technologies Corporation - OpTmizer™ CTS™ T-Cell Expansion SFM

Device Name: OpTmizer™ CTS™ T-Cell Expansion SFM

Common/Usual Name: OpTmizer

Classification Name: Tissue culture media for human *ex vivo* tissue and cell culture processing applications (per 21 CFR § 876.5885)

Product Code: NDS

Submitter: Life Technologies Corporation
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Date Prepared: November 30, 2011

Predicate Device:

Trade Name	Manufacturer	510(k)
AIM-V® Medium	Life Technologies Corporation	K022086

Intended Use

OpTmizer™ CTS™ T-Cell Expansion SFM is a liquid tissue culture media product intended for human *ex vivo* tissue and cell culture processing applications.

Substantial Equivalence

AIM-V® Medium is the predicate device for tissue culture media intended for human *ex vivo* tissue and cell culture processing applications. It is composed of chemically defined nutrient materials in solution (with or without supplements) that are essential for the survival and development of tissue or cells of human or other animal origin. These nutrients are provided in liquid form for use in supporting the growth or maintenance of human tissue and cells.

A. Intended Uses

OpTmizer™ CTS™ T-Cell Expansion SFM tissue culture product is intended for human *ex vivo* tissue and cell culture processing applications. These devices are chemically defined tissue culture media used to support the growth or maintenance of human tissue or cells in culture.

B. Principles of Operation and Technological Characteristics

OpTmizer™ CTS™ T-Cell Expansion SFM has been developed for the growth and expansion of human T lymphocytes. OpTmizer™ CTS™ T-Cell Expansion SFM is a complete serum-free and xeno-free 1X medium consisting of the OpTmizer™ T-Cell Expansion Basal Medium with the addition of the OpTmizer™ T-Cell Expansion Supplement. OpTmizer™ CTS™ T-Cell Expansion Medium is designed for the expansion of CD3+ densities of > 3×10^6 cells/mL in static conditions and > 2×10^7 cells/ML in Wave bags.

C. Pre- Clinical Testing

Performance standards under Section 514 of the Federal Food, Drug, and Cosmetic Act have been established in "Class II Special Controls Guidance Document: Tissue Culture Media for Human *Ex Vivo* Tissue and Cell Culture Processing Applications; Final Guidance for Industry and FDA Reviewers," issued May 16, 2001. The specific assay tests and Life Technologies Corporation's equivalent tests are noted in the following table.

Special Control Objective	**Life Technologies Corporation OpTmizer™ CTS™ T-Cell Expansion SFM**
Demonstrate lack of potential toxicity of materials in the media to cells or tissue and demonstrate support of tissue and cell growth	OpTmizer QC Performance Assay
Demonstrate lack of endotoxin or pyrogen contamination	Limulus Ameobocyte (LAL) test (25 USP Monograph <85>)
Validation of Aseptic Processing and Sterility Assurance Level (SAL)	Determination of SAL to be $\geq 10^{-3}$ compliance with GMP requirements regarding aseptic processing
Demonstrate Chemical purity	Incoming Raw Material testing using USP, ACS, FCC, GIBCO, or Cell Culture requirements

D. Stability/Shelf-Life

Life Technologies Corporation performs shelf life testing for StemPro® MSC SFM Medium using retained product stored at 2° - 8° C. In addition, a minimum of one new production lot of OpTmizer™ CTS™ T-Cell Expansion SFM is tested each year to verify that the product continues to meet the established shelf life. Based on analysis of product performance over time, Life Technologies Corporation has established a shelf life of twelve months for the OpTmizer™ CTS™ T-Cell Expansion SFM formulation. Stability testing involves the assessment of these functional aspects of media, including demonstrating: (1) that the pH continues to meet specifications; and (2) the media is not cytotoxic and supports the growth of mammalian cells. The pH is tested to demonstrate that the media is not chemically altered during its storage. In assessing cytoxicity, Life Technologies Corporation demonstrates

that the media functions in supporting the growth of mammalian cells and that the media does not become toxic to mammalian cells during storage.

In addition, results from the studies indicate the container/closure system provides protection from microbial contamination.

E. Conclusion

OpTmizer™ CTS™ T-Cell Expansion SFM and AIM-V® Medium are used for human *ex vivo* tissue and cell culture processing applications and have the same principles of operation, technological characteristics, efficacy (generic cellular growth and maintenance) and safety (consistency in chemical content and formulation, biocompatibility with cells, and purity). Their efficacy in supporting the survival, growth, development, and maintenance of human cells or tissue culture systems has been well established in scientific publications. Both products (OpTmizer™ CTS™ T-Cell Expansion SFM and AIM-V® Medium) are manufacturer in accordance with QSR requirements and are labeled as aseptically processed. Thus, OpTmizer™ CTS™ T-Cell Expansion SFM is substantially equivalent to the legally marketed device intended for the human *ex vivo* tissue and cell culture processing applications.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

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GRAND ISLAND NY 14072

JUN 2 1 2012

Re: K113566
Trade/Device Name: OpTmizer™ CTS™ T-Cell Expansion Serum Free Medium
Regulation Number: 21 CFR§ 876.5885
Regulation Name: Tissue culture media for human ex vivo tissue and cell culture
Regulatory Class: II
Product Code: NDS
Dated: June 11, 2012
Received: June 12, 2012

Dear Dr. Tanzella:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K113566

Device Name: OpTmizer™ CTS™ T-Cell Expansion Serum Free Medium

Indications for Use:

OpTmizer™ CTS™ T-Cell Expansion Serum Free Medium is a liquid tissue culture medium products intended for human *ex vivo* tissue and cell culture processing applications.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHRE PAGE IF NEEDED)

Concurrence of CDRH, Office of Evaluation (ODE)

Prescription Use X OR Over-The –Counter Use_____
(Per 21 CFR 801.109) (Optional Format 1-2-96)

(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K113566